Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. – 135. (Cancelled).

136. (Currently amended) A method of treating a subject in need comprising administering to the subject an effective amount of a composition, wherein:

(a) the composition comprises particles of fenofibrate ~~**or a salt thereof**~~ having an effective average particle size of less than about ~~**2000**~~ **1200** nm **and at least one surface stabilizer**;

(b) **the fenofibrate particles present in the composition redisperse in a biorelevant media; and**

(c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:

(i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and

(ii) a 90% Confidence Interval for C_{max}, which is between 0.80 and 1.25

~~**there is no substantial difference between the AUC of the composition when administered to a human subject under fed as compared to fasted conditions; and**~~

~~**(c) there is no substantial difference between the C_{max} of the composition when administered to a human subject under fed as compared to fasted conditions**~~.

137. (Cancelled).

138. (Cancelled)

139. (Cancelled)

140. (Currently amended) The method of claim 136, wherein the composition is bioequivalent to a micronized ~~TRICOR®~~ 54 mg fenofibrate oral solid dosage form.

141. (Currently amended) The method of claim 136, wherein the composition is bioequivalent to a micronized ~~TRICOR®~~ 160 mg fenofibrate oral solid dosage form.

142. (Previously presented) The method of claim 141, wherein the composition is a single daily dose.

143. (Currently amended) The method of claim 136, wherein the composition is bioequivalent to a micronized ~~TRICOR®~~ 200 mg fenofibrate oral solid dosage form.

144. (Previously presented) The method of claim 143, wherein the composition is a single daily dose.

145. (Previously presented) The method of claim 136, wherein the difference in AUC of the fenofibrate composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than about 35%, less than about 30%, less than about 25%, less than about 20%, less than about 15%, less than about 10%, less than about 5%, and less than about 3%.

146. (Previously presented) The method of claim 136, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139 μg/mL.h.

147. (Previously presented) The method of claim 136, wherein the composition exhibits a T_{max} after administration to fasting human subjects selected from the group consisting of less than about 6 hours, less than about 5 hours, less than about 4 hours, less than about 3 hours, less than about 2 hours, less than about 1 hour, and less than about 30 minutes.

148. (Currently amended) The method of claim 136, wherein in comparative pharmacokinetic testing with a ~~TRICOR®~~ **micronized fenofibrate** 160 mg tablet or **micronized fenofibrate** 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate, the composition exhibits a T_{max} selected from the group

consisting of less than about 90%, less than about 80%, less than about 70%, less than about 50%, less than about 30%, and less than about 25% of the T_{max} exhibited by the ~~**TRICOR®**~~ **micronized fenofibrate** tablet or capsule.

149. (Previously presented) The method of claim 136, wherein the fenofibrate or a salt thereof is present in the composition in an amount selected from the group consisting of:

(a) about 50 to about 500 g/kg fenofibrate or a salt thereof per kg of composition;

(b) about 100 to about 300 g/kg fenofibrate or a salt thereof per kg of composition;

(c) about 200 to about 225 g/kg fenofibrate or a salt thereof per kg of composition; and

(d) about 119 to about 224 g/kg fenofibrate or a salt thereof per kg of composition.

150. (Currently amended) The method of claim 136, wherein the composition comprises a dosage of about 145 mg of particles of fenofibrate or a salt thereof, wherein:

(a) the dosage is therapeutically effective; and

(b) the composition is bioequivalent to a ~~**TRICOR®**~~ **micronized fenofibrate** 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{max} and AUC ~~**or a 90% Confidence Interval of between 0.80 and 1.25 for AUC and a 90% Confidence Interval of between 0.70 to 1.43 for C_{max}**~~.

151. (Currently amended) The method of claim 136, wherein the composition comprises a dosage of about 48 mg of particles of fenofibrate or a salt thereof, wherein:

(a) the dosage is therapeutically effective; and

(b) the composition is bioequivalent to a ~~**TRICOR®**~~ **micronized fenofibrate** 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{max} and AUC ~~**or a 90% Confidence Interval of between 0.80 and 1.25 for AUC and a 90% Confidence Interval of between 0.70 to 1.43 for C_{max}**~~.

152. (Currently Amended) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate ~~**or a salt thereof**~~, wherein following

administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

153. (Currently Amended) The method of claim 152, wherein following administration of the composition **comprising a dosage of about 160 mg of fenofibrate** to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

154. (Currently Amended) The method of claim 152, wherein following administration of the composition **comprising a dosage of about 160 mg of fenofibrate** to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

155. (Currently Amended) The method of claim 152, wherein following administration of the composition **comprising a dosage of about 160 mg of fenofibrate** to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

156. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

(a) 1.0 mg/mL at one hour;
(b) 6.5 mg/mL at two hours;
(c) 7.0 mg/mL at three hours; and
(d) 1.5 mg/mL at twenty-four hours.

157. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

158. (Currently Amended) The method of claim 157, wherein following administration of the composition **comprising a dosage of about 160 mg of fenofibrate** to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

159. (Previously presented) The method of claim 157, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

160. (Currently Amended) The method of claim 157, wherein following administration of the composition **comprising a dosage of about 160 mg of fenofibrate** to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

161. (Currently Amended) The method of claim 157, wherein following administration of the composition **comprising a dosage of about 160 mg of fenofibrate** to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

162. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

(a) 4.5 mg/mL at one hour;

(b) 3.0 mg/mL at two hours;

(c) 6.0 mg/mL at four hours;

(d) 6.5 mg/mL at five hours; and

(e) 1.5 mg/mL at twenty-four hours.

163. (Previously presented) The method of claim 136, wherein the fenofibrate or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

164. (Currently amended) The method of claim 136, wherein the effective average particle size of the particles of fenofibrate or a salt thereof are selected from the group consisting of less ~~than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm,~~ less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm,

less than about 200 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

165. (Previously presented) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a D_{99} of less than about 500 nm.

166. (Previously presented) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a D_{50} of less than about 350 nm.

167. (Previously presented) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a mean particle size of less than about 100 nm.

168. (Previously presented) The method of claim 136, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, opthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

169. (Previously presented) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

170. (Previously presented) The method of claim 169, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

171. (Previously presented) The method of claim 170, wherein the composition is formulated into a tablet dosage form.

172. (Previously presented) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

173. (Previously presented) The method of claim 136, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

174. (Previously presented) The method of claim 136, wherein within about 5 minutes at least about 20%, at least about 30%, or at least about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

175. (Previously presented) The method of claim 136, wherein within about 10 minutes at least about 40%, at least about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

176. (Previously presented) The method of claim 136, wherein within about 20 minutes at least about 70%, at least about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

177. (Previously presented) The method of claim 136, wherein:

(a) within about 5 minutes at least about 30% of the composition is dissolved;

(b) within about 10 minutes at least about 70% of the composition is dissolved; and

(c) within about 20 minutes at least about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

178. (Previously presented) The method of claim 136, wherein:

(a) within about 5 minutes at least about 40% of the composition is dissolved;

(b) within about 10 minutes at least about 80% of the composition is dissolved; and

(c) within about 20 minutes at least about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

179. (Currently amended) The method of claim 136, wherein upon administration, the composition redisperses such that the redispersed particles of fenofibrate or a salt thereof have an effective average particle size of less than about ~~2 microns~~ **1200 nm**.

180. (Currently amended) The method of claim 179, wherein the redispersed particles of fenofibrate or a salt thereof have an effective average particle size selected from the group consisting of ~~less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm,~~ less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

181. (Currently amended) The method of claim 136, wherein the composition redisperses in a biorelevant media such that the redispersed particles of fenofibrate or a salt thereof have an effective average particle size of less than about ~~2 microns~~ **1200 nm**.

182. (Currently amended) The method of claim 181, wherein the redispersed particles of fenofibrate or a salt thereof have an effective average particle size selected from the group consisting of ~~less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm,~~ less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

183. (Previously presented) The method of claim 136, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

184. (Previously presented) The method of claim 136, wherein the subject is a human.

185. (Previously presented) The method of claim 136, wherein the method is used to treat a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, and peripheral vascular disease .

186. (Previously presented) The method of claim 136, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

187. (Previously presented) The method of claim 136, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

188. (Previously presented) The method of claim 136, wherein the method is used to decrease the risk of pancreatitis.

189. (Previously presented) The method of claim 136, wherein the method is used to treat indications where lipid regulating agents are typically used.

190. (New) The method of claim 136, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.

191. (New) The method of claim 136, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.

192. (New) The method of claim 136, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene

sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β-D-glucopyranoside; n-decyl β-D-maltopyranoside; n-dodecyl β-D-glucopyranoside; n-dodecyl β-D-maltoside; heptanoyl-N-methylglucamide; n-heptyl-β-D-glucopyranoside; n-heptyl β-D-thioglucoside; n-hexyl β-D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl β-D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl-β-D-glucopyranoside; octyl β-D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C_{12-15}dimethyl hydroxyethyl ammonium chloride, C_{12-15}dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl $(ethenoxy)_4$ ammonium chloride, lauryl dimethyl

(ethenoxy)$_4$ ammonium bromide, N-alkyl (C_{12-18})dimethylbenzyl ammonium chloride, N-alkyl (C_{14-18})dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C_{12-14}) dimethyl 1-napthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C_{12-14}) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C_{12} trimethyl ammonium bromides, C_{15} trimethyl ammonium bromides, C_{17} trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, POLYQUAT 10™, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, MIRAPOL™, ALKAQUAT™, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

193. (New) The method of claim 136, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.